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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,665	01/08/2004	Dennis A. Carson	103.014US3	8816

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,665	CARSON ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/18/04; 1/8/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Informalities

The following informalities are noted and should be corrected to place the claims in proper form:

Claims 3-8 should be amended to end in periods.

Claims 13 and 14, the word "a", occurring immediately after "the", should be deleted.

Duplicate Claim Warning

Claim 9 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 10. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Accordingly, this situation should be rectified at Applicant's earliest convenience to avoid any potential future objection on this basis.

Improper Dependent Claim

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1, from which claim 13 depends, already recites administration to a mammal which is a human afflicted with leukemia. Accordingly, the recitation of claim 13 that "the a" mammal is a human is non-limiting.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis for the term "concentration" in claims 3 and 4; claims 1 and 2 from which they depend claim amounts *per se* (i.e. 50 to 5000mg), not concentrations.

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Rejections

1) Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,545,034 in view of Spiegelman et al (USP 6,552,055).

2) Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 10 and 12-23 of copending Application No. 10/682,790 in view of Spiegelman et al (USP 6,552,055).

This is a provisional obviousness-type double patenting rejection.

3) Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting rejection as being unpatentable over claims 10, 14-20, 49, 50 and 52-54 of copending Application No. 09/634,207.

This is a provisional obviousness-type double patenting rejection.

Discussion

Since the issues involved are largely cumulative, the three rejections above will be discussed together in the interest of economy.

USP 6,545,034, USSN 10/682,790, USSN 09/634,207, and instant claims 1-20 all recite obvious variations of the same treatment. Slight differences in language, e.g. "reducing the viability" or "increasing the susceptibility" of the leukemia cells, are viewed as describing what is in all cases essentially the same method, namely treatment of leukemia with etodolac compounds.

The secondary reference, Spiegelman et al (USP 6,552,055), is cited to demonstrate the conventional nature of the various particular treatment features recited in certain claims, e.g. determination of a suitable/optimal dosage range/concentration, administration via oral or parenteral routes, enteric coating to provide delayed release, single or divided doses, etc. See the secondary reference at the passage spanning col. 17, line 22 to col. 18, line 40; and col. 21, lines 3-9. Note that leukemia is recognized as a cancer "high" in PPAR-y, as it is described in some of the claims of the conflicting, copending applications. (See col. 2, lines 8-20 and lines 53-58; col. 9, lines 21-35; and col. 11, lines 16-36.) Similarly, the use of co-therapeutic agents to

modify therapeutic response, including alkylating agents such as cyclophosphamide, is also well-known in the cancer art. (See col. 3, lines 39-45 and col. 16, lines 58-64).

The secondary reference is cited as demonstrating the state of the cancer art and as such is general in nature, differing from the instant claims insofar as it does not specify the use of etodolac compounds. It does clearly support the well-established legal principle, however, that it is generally obvious to determine workable and/or optimal conditions for carrying out a claimed method using no more than routine experimentation. See for example In re Aller, 105 USPQ 233, 235 (1955). It would have been obvious to have determined workable and/or optimal dosages/concentrations, dosage routes and dosage forms, and to have modified such therapies with known co-therapeutic agents such as alkylating agents, motivated by the desire to provide the best treatment for a particular patient and/or condition. Such modifications are routine in the chemotherapeutic art as illustrated by Spiegelman et al and would require the application of no more than routine skill, consonant with the reasoning of the Aller decision.

Finally, it is noted for the record that it is well-known in the art that the active isomer of etodolac in the treatment of cancer is 1-(R). See for example USP 5,955,504.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614